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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,831	08/02/2001	Brigitte Bathe	211736US0X	7640
22850	7590	01/14/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.			KERR, KATHLEEN M	
1940 DUKE STREET			ART UNIT	
ALEXANDRIA, VA 22314			PAPER NUMBER	

1652

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/919,831

**Applicant(s)**

BATHE ET AL.

**Examiner**

Kathleen M Kerr

**Art Unit**

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 34-58 is/are pending in the application.
- 4a) Of the above claim(s) 49-58 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 34 and 36-44 is/are allowed.
- 6) ☒ Claim(s) 45-48 is/are rejected.
- 7) ☒ Claim(s) 35 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

## **DETAILED ACTION**

### ***Application Status***

1. In response to the previous Office action, a non-Final rejection (mailed on July 18, 2003), Applicants filed a response and amendment received on October 20, 2003. Said amendment cancelled Claims 1-33 and added new Claims 34-58. Thus, Claims 34-58 are pending in the instant Office action.

### ***Election***

2. Claims 49-58 are drawn to non-elected subject matter per the previous restriction requirement and are withdrawn from consideration. Claims 34-48 will be examined herein.

### ***Priority***

3. Certified translation of foreign priority documents 100 43 335.9 filed in Germany on September 2, 2000 and 101 09 688.7 filed in Germany on July 28, 2001 have been received. Claims 34-48 have support in these documents and, thus, are granted an earliest effective filing date of September 2, 2000 in the instant Office action.

### ***Withdrawn - Objections to the Specification***

4. Previous objection to the specification because the title is not descriptive is withdrawn by virtue of Applicants' amendment.

***Maintained - Objections to the Specification***

5. Previous objection to the Abstract for not completely describing the disclosed subject matter (see M.P.E.P. § 608.01(b)) is maintained. Applicants have presented no arguments except to amend the Abstract; the amendment is inadequate because the species, *Corynebacterium glutamicum*, is missing as well as mention of the other disclosed protein, metR, a transcriptional activator (as described in the specification). Correction is required.

***Withdrawn - Objections to the Claims***

6. Previous objection to Claims 1-3, 5-7 and 16 as containing non-elected subject matter is withdrawn by virtue of Applicants' cancellation of said claims.

7. Previous objection to Claim 5 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn by virtue of Applicants' cancellation of said claim.

8. Previous objection to Claim 4 as depending from a rejected claim, Claim 1, is withdrawn by virtue of Applicants' cancellation of said claim.

***Withdrawn - Claim Rejections - 35 U.S.C. § 112***

9. Previous rejection of Claims 1-3, 5, 6, and 16 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "of coryneform bacteria" is withdrawn by virtue of Applicants' cancellation of said claims. Moreover, new claims do not contain this phrase.

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10. Previous rejection of Claims 1-3, 5, 6, and 16 under 35 U.S.C. § 112, second paragraph, as being indefinite for Item e) in Claim 1 is withdrawn by virtue of Applicants' cancellation of said claims. Moreover, new claims do not contain this phrase.

11. Previous rejection of Claims 5-6 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "within the range of degeneration of the genetic code", the phrase "and optionally", and the phrase "sense mutations of neutral function in (i)" is withdrawn by virtue of Applicants' cancellation of said claims. Moreover, new claims do not contain this phrase.

12. Previous rejection of Claim 16 under 35 U.S.C. § 112, second paragraph, as being indefinite is withdrawn by virtue of Applicants' cancellation of said claims.

13. Previous rejection of Claims 1-3, 5, 6, and 16 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicants' cancellation of said claims.

14. Previous rejection of Claims 1-3, 5, 6, and 16 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicants' cancellation of said claims.

***Withdrawn - Claim Rejections - 35 U.S.C. § 102***

15. Previous rejection of Claims 1-3, 5, 6, and 16 under 35 U.S.C. § 102(a) as being anticipated by Pompejus *et al.* (WO 01/00843) is withdrawn by virtue of Applicants' cancellation of said claims. Moreover, the filing of certified translation of priority documents in the instant case renders Pompejus *et al.* not prior art since its publication does not pre-date the earliest effective filing date of the pending claims herein.

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16. Previous rejection of Claims 1-2 and 5-6 under 35 U.S.C. § 102(b) as being anticipated by Johnston *et al.* is withdrawn by virtue of Applicants' cancellation of said claims.

## **NEW ISSUES**

### ***Claim Objections***

17. Claim 35 is objected to for improper English. The phrase "wherein is" is improper; a noun is required within this phrase. Correction is required.

18. Claim 45 is objected to for improper English and a spelling error. In line 3, "Succinylhomoserine" should not be capitalized. Also in line 3, "sulfhydralase" is misspelled; the correct spelling is ---sulfhydrylase---. In line 5, the phrase "a temperature of a from" is improper. Correction on all these points is required.

### ***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

19. Claim 48 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. From the claim language, it is unclear if a fragment of the complement is considered part of the scope of the claim, or if the full complement in its entirety only is within the metes and bounds. Clarification is required.

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The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

20. Claims 45-47 are rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for polynucleotides that encode SEQ ID NO:3, does not reasonably provide enablement for polynucleotides with such low sequence identity, such as the weakly stringent hybridization conditions claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The amount of experimentation required of one of skill in the art to use the claimed invention to the full extent of its scope is undue.

The factors to be considered in determining whether undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or

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absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a prima facie case is discussed below.

Applicants present no guidance or working examples of the use of polynucleotides that have such low sequence identity with respect to SEQ ID NO:1. The nature of the invention is such that the DNA encodes a protein product, metZ – O-succinylhomoserine sulphydrylase, whose attenuation is useful in the biosynthesis of amino acids; and with such a great deviation from the known sequence, the predictability of retaining this same functionality becomes extremely low. No examples of other O-succinylhomoserine sulphydrylases, with or without sequence information, are described in the specification for comparison to the disclosed metZ from *C. glutamicum*. Such enormous breadth and unpredictability renders the instant claims not enabled to the full extent of their scope without undue experimentation.

Additionally, while the instant specification describes and enables means for identifying other metZ genes using hybridization methods, etc., these methods do not enable one of skill in the art to make all, or a relevant portion of, the polynucleotides within the scope of the claims because the ability to find a metZ gene, which is structurally related to SEQ ID NO:1, is not equivalent to the ability to make a metZ gene as required by the statute (i.e., “make and use”). No description in the specification or the art provides particular residues whose encoding is important within the disclosed sequence so that its metZ-nature is maintained. Thus, one of skill in the art would be unable to predict the structure of the other members of the genus in order to



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make such members. Therefore, the instant claims are not enabled to the full extent of their scope.

### ***Other Relevant Art***

21. The Examiner previously noted Nakagawa *et al.* (EP 1108790 from the IDS) and its disclosure relative to the claims. The Examiner also herein notes Nakagawa *et al.* (USPAP 2002/0197605), which is a related U.S. application disclosing the same. However, this USPAP is not considered prior art because its filing date (December 18, 2000) does not pre-date the effective filing date in the instant application (September 2, 2000). As previously noted,

“Nakagawa *et al.* (EP 1108790 – see IDS) teach a polynucleotide (sequence 7068) that is 100% identical to SEQ ID NO:1 in the instant application (see attached alignment), which, therefore, encodes SEQ ID NO:3 exactly. Nakagawa *et al.* also teach vector and host cells containing the disclosed sequences, particularly coryneform host cells (see page 22).”

### ***Summary of Pending Issues***

22. The following is a summary of the issues pending in the instant application:
- a) The Abstract stands objected to for not completely describing the disclosed subject matter.
  - b) Claim 35 stands objected to for improper English.
  - c) Claim 45 stands objected to for improper English and a spelling error.
  - d) Claim 48 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.
  - e) Claims 45-47 stand rejected under 35 U.S.C. § 112, first paragraph, scope of enablement.

### ***Conclusion***

23. Claims 34 and 36-44 are allowed; Claim 35 is objected to. Claims 45-48 are rejected for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

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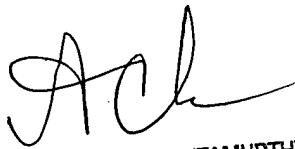
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
PONNATHAPU ACHUTAMURTHY  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

  
Kathleen M Kerr  
Examiner  
Art Unit 1652

January 8, 2004